2:30 p.m.

## 850-3 Does Periprocedural Creatine Kinase Release Predict Adverse Outcomes After Intracoronary Radiation Therapy for In-Stent Restenosis?

Ron Waksman, Arvind K. Sharma, Andrew E. Ajani, Edouard F. Cheneau, Augusto D. Pichard, Lowell F. Satler, Ellen Pinnow, Afework GebreEyesus, Rebecca Torguson, Joseph Lindsay, Washington Hospital Center, Washington, DC

**Background:** Peri-procedural Creatine Kinase (CKMB) after PCI was reported to be associated with increased mortality. However its impact on patients treated with in-stent restenosis (ISR) and intracoronary radiation therapy (IRT) is unknown. **Methods:** We evaluated 1168 patients who were enrolled in radiation trials for ISR using gamma and beta emitters. Patients were analyzed according to the degree of CKMB rise within 24 hours of the index IRT procedure [>4 x baseline, 2-4 x baseline, and < 2x baseline (normal)]. **Results:** Patients with CKMB>4x were older (64 ± 12 years, p=0.006), had a higher rate of multivessel disease (41%, p=0.044), and were more likely treated with excimer laser (38%, p<0.001). The cohort with the highest CKMB release (CKMB>4x) had significantly higher rates of adverse clinical events at 6 months; including late thrombosis.

| | CKMB >4x (*N*=177) | CKMB 2-4x (*N*=161) | CKMB <2x (Normal) (*N*=830) | *P* |
|---|---|---|---|---|
| In-hospital MACE (Death, Q-Wave MI, TLR), % | 11.7 | 3.4 | 0.6 | <0.001 |
| **6-month events** | | | | |
| Death, % | 4.9 | 1.4 | 2.0 | 0.067 |
| Q-Wave MI, % | 3.7 | 1.4 | 0.6 | 0.004 |
| TLR, % | 20.1 | 19.4 | 12.2 | 0.007 |
| TVR, % | 26.8 | 30.2 | 18.0 | <0.001 |
| Late Thrombosis, % | 9.8 | 1.4 | 1.6 | <0.001 |
| Late Total Occlusion, % | 11.0 | 8.6 | 3.5 | <0.001 |
| MACE, % | 22.0 | 20.1 | 13.2 | 0.006 |

**Conclusions:** Post-procedural CKMB elevation is of prognostic importance in patients treated with IRT for ISR, and its analysis appears mandatory to risk stratify these patients.

2:45 p.m.

## 850-4 The Radiance P-32 RDX Balloon in Saphenous Vein Grafts: A Comparison of De-Novo and In-Stent Restenotic Lesions in the SVG Brite Trial

Costantino O. Costantini, Alexandra J. Lansky, Kazuyuki Shirai, Ecaterina Cristea, Horia Marginean, Cristina Ispas, Brian Proctor, Moses Tarawali, Mark G. Midei, Maurice Buchbinder, Roxana Mehran, George Dangas, Jeffrey M. Moses, Martin B. Leon, Gregg W. Stone, Cardiovascular Research Foundation, New York, NY

**Background**: Vascular brachytherapy (VBT) has been shown to be efficacious in the treatment of ISR but not denovo (DN) native coronary lesions. The relative efficacy of beta VBT in DN and ISR lesions *in SVGs* is not known. **Methods**: In SVG BRITE 49 pts with single lesions (25 DN, 24 ISR) in diseased SVGs were treated with the Radiance RDX P32 balloon (33 mm encapsulated foil source delivering 20 Gy 1mm into the vessel wall) after successful PCI. Clinical and angiographic FU was obtained at 6 months in all pts. QCA included analysis of the radiation edge (RE) fall-off zones and geographic miss (GM). **Results**: Baseline characteristics were well matched, mean lesion length was 13 mm, and vessel size was 3.31 mm. A new stent was implanted in 88% of DN and 32% of ISR lesions. The final MLD (2.71±0.5 vs. 2.66±0.5, p=0.7) and %DS (20±9% vs. 22±10, p=0.3) were similar. GM for both DN and restenotic pts was infrequent proximally (8.3% vs. 4.0%, p=NS) and distally (4.2% vs. 0%, p=NS) respectively. There were no deaths, Q-wave MIs or stent thromboses. Clinical and angiographic restenosis (RS) rates appear in the table. **Conclusions**: Beta VBT with the RDX P32 balloon of both DN and ISR SVG lesions results in low recurrence rates, especially in DN lesions. Restenosis solely outside the stent confines was uncommon, likely due to infrequent GM. Larger scale evaluation of this technology in SVGs is warranted.

| 6 month results | De Novo | Restenotic | p Value |
|---|---|---|---|
| Lesion RS (%) | 11.8 | 30.0 | 0.24 |
| Stent RS (%) | 11.8 | 25.0 | 0.41 |
| Prox Edge RS (%) | 16.7 | 18.8 | 0.72 |
| Dist Edge RS (%) | 11.8 | 5.0 | 0.58 |
| TLR (%) | 4.3 | 26.1 | 0.095 |
| TVR (%) | 4.3 | 26.1 | 0.095 |

3:00 p.m.

## 850-5 Repeat Intracoronary Gamma Radiation for Patients With In-Stent Restenosis Who Failed Radiation Therapy

Ron Waksman, Andrew E. Ajani, Lowell F. Satler, Kenneth M. Kent, Michael Parrazzo, Neil J. Weissman, Robert Lew, Rebecca Torguson, Edouard F. Cheneau, Ellen Pinnow, Daniel A. Canos, Augusto D. Pichard, Washington Hospital Center, Washington, DC

**Background:** Intracoronary radiation (IR) is an effective therapy in preventing recurrences of in-sent restenosis (ISR). However, nearly 20% of the patients (pts) enrolled in radiation studies for ISR required repeat revascularization to the irradiated site. Re-WRIST (*W*ashington *R*adiation for *I*n-*S*tent Restenosis *T*rial) is a registry evaluating the safety and efficacy of re-treatment with IR in pts with refractory ISR.
**Methods:** Twenty-four patients with ISR who had recurrence of stenosis at the previously irradiated segment and who failed a subsequent angioplasty were eligible for re-treatment with IR if considered a poor surgical candidate. In Re-WRIST the radiation system was a nylon ribbon containing $^{192}$Ir seeds delivered into a non-centered end lumen catheter. The prescribed dose was 15 Gy at 2 mm. The antiplatelet regimen post-procedure was 6 months of clopidogrel. Patients were followed clinically and angiographically.
**Results:** At present, 19 pts have completed 6 months follow-up. The mean age was 65.4 + 7.7 yrs, 62.5% male, 43.5% diabetic, and 87% had previous CABG. Lesions were in native coronary arteries (n=17), saphenous vein grafts (n=5), and 2 in the left internal mammary graft. The mean time interval between the two radiation treatments is 16.6 ± 7.6 months and the mean number of previous interventions to the target lesion was 4.8 ± 2.7. The utiliziation of devices during the intervention was balloon alone in 10, excimer laser in 6, atherectomy in 1, and restenting in 7 pts. At 30 days one patient required reintervention. At 6 months, 5 patients had target lesion revascularization and none had an MI. Overall, 14 patients are event free. To date, there are no clinical or angiographic complications (evidence of aneurysm, fibrosis, perforation) in any of the patients.
**Conclusions:** Repeat radiation to the same site using $^{192}$Ir for refractory ISR is safe and effective. Complete 9-month clinical and angiographic follow-up for the entire cohort will be available at presentation.

3:15 p.m.

## 850-6 Cumulative Effect of High Radiation Dose and Prolonged Antiplatelet Therapy in Improving Outcomes of Patients Treated With Vascular Brachytherapy

Edouard F. Cheneau, Andrew E. Ajani, Roswitha Wolfram, Rebecca Torguson, Augusto D. Pichard, Lowell F. Satler, Regina Deible, Ellen Pinnow, Afework GebreEyesus, Joseph Lindsay, Ron Waksman, Washington Hospital Center, Washington, DC

**Background:** Vascular brachytherapy (VBT) reduces the recurrence of in-stent restenosis (ISR). The optimal radiation dose and the anti-thrombotic regimen remain debated.
**Methods:** 240 patients with diffuse ISR in native coronary arteries (lesion length 36-80 mm) underwent angioplasty and were enrolled in the Washington Radiation for In-Stent Restenosis Trial for long lesions (Long WRIST). Of these, 120 patients were randomized for either radiation with $^{192}$Ir with 15 Gy at 2 mm from the source or placebo. The additional 120 patients were treated with $^{192}$Ir with 18 Gy. Of these, the first 60 were treated with one month of Anti-Platelet Therapy (APT) while the second 60 patients of the 18 Gy group recieved 6 months of APT. Six months follow-up included angiography and clinical outcomes: target lesion revascularization (TLR) and major adverse cardiac events (MACE).
**Results:** All 240 pts underwent successful IRT therapy. Radiation with 15 Gy reduces the recurrence of angiographic restenosis and MACE (Table). A high dose of 18 Gy further reduces restenosis and the event rate. Late thrombosis after VBT was similar to control with prolonged APT up to 6 months. Overall, 18 Gy and 6 months of APT resulted in 86.7% of patinets free of cardiac event at 6 months, as compared to 40% in the placebo group.

| **Radiation dose, Gy** | **0** | **15** | **18** | **18** |
|---|---|---|---|---|
| **APT treatment, months** | **1** | **1** | **1** | **6** |
| TLR, % | 58.3 | 30* | 18.3 | 13.3 |
| Late thrombosis, % | 5 | 10 | 6.6 | 3.3 |
| MACE, % | 60 | 33.3* | 18.3† | 13.3† |

* p<0.05 15 Gy vs 0 Gy, † p<0.05 18 Gy vs 15 Gy

**Conclusions:** A radiation dose of 18 Gy with prolonged APT optimizes the outcome of patients treated for diffuse ISR with $^{192}$Ir VBT.